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EXAMINER

STEELE, AMBER D

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1639

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Continued

The amendment filed January 12, 2009 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because of the following:

a. The proposed amendment requires further consideration and/or search (e.g. the new limitation “wherein said second layer is substantially free of PVP when said first layer comprises PVP and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP” of claim 40, etc.).

b. The proposed amendment may necessitate the modification of outstanding rejection(s) to address the new limitation (e.g. the new limitation “wherein said second layer is substantially free of PVP when said first layer comprises PVP and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP” of claim 40, etc.).

c. The proposed amendment may necessitate the raising of new prior art rejections (e.g. the new limitation “wherein said second layer is substantially free of PVP when said first layer comprises PVP and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP” of claim 40, etc.).

d. The proposed amendment may necessitate the raising of new 112 issues (e.g. the new limitation “wherein said second layer is substantially free of PVP when said first layer comprises PVP and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP” of claim 40, etc.).

e. There is no convincing evidence under 37 CFR 1.116(b) why the proposed amendment was not earlier presented.

f. Applicants arguments of the prior art of record are moot, in part, since the arguments are based on the proposed amendments that have not been entered (see below for the response to arguments not based on the proposed amendments).

g. For all the reasons above, the amendment does not place the application in better condition for allowance and/or appeal.

Withdrawn Rejection

The rejection of claim 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (i.e. new matter) is withdrawn in view of the support provided by applicants in the response received on January 12, 2009 (i.e. page 9, paragraph 3; page 12, paragraphs 4 and 5 of the originally filed specification).

Arguments and Response

Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Young et al. for claims 40, 42-47, and 53-59 were considered but are not persuasive for the following reasons.

Applicants contend that Young et al. do not teach a two layer gel. Please note: arguments based on the proposed claim amendments which have not been entered (e.g. the new limitation "wherein said second layer is substantially free of PVP when said first layer comprises PVP and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP" of claim 40, etc.) are not addressed.

Applicants' arguments are not convincing since the teachings of Young et al. anticipate the device of the instant claims. Young et al. teach a PVP-agarose gel (please refer to the entire specification particularly page 1972). Regarding applicants' contention that Young et al. do not

teach a two layer device, it is noted that the two layers as presently claimed are not necessarily structurally different. The "first layer" comprises PVP or PVPP (see present claim 1) and further comprises (a) CTAB, EDTA, EGTA, cyclodextrins, proteins, polypeptides, antibodies, aptamers, lectins, nucleic acids, or ion-exchangers (see present claim 43) and/or (b) a sample loading means (see present claim 46). While the "second layer" must be substantially free of PVP, PVPP, CTAB, EDTA, EGTA, cyclodextrins, proteins, polypeptides, antibodies, aptamers, lectins, nucleic acids, or ion-exchangers (see present claim 44) and may consist of "agarose, Sepharose™, Sephadex™, Sephacryl™, BioGel™, Superose™, or acrylamide" (see present claim 53). In addition, the first or second layer must be arranged such that the first layer is above the second layer, the first layer is a "first phase of a gel", and the second layer is a "second phase of a gel" (see present claim 40). Therefore, the presently claimed invention reads on various species of device including a PVP-agarose gel wherein the first phase (i.e. first layer) is above a second phase (i.e. second layer). For example, the first phase could be designated as the section of the gel separating nucleic acids larger than 600 kbp and the second phase could be designated as the section of the gel separating nucleic acids smaller than 600 kbp (see present Figure 5B as an example). Alternatively, the first phase of the gel could be the sample loading area and the second phase of the gel could be the area wherein the samples run (see Figure 1 of Young et al.).

Arguments and Response

Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Coffman and Berthelet et al. for claims 40, 42-46, and 53-59 were considered but are not persuasive for the following reasons.

Applicants contend that neither Coffman nor Berthelet et al. teach a device with two layers in which the first layer is adapted to bind or inactivate inhibitors of the activity of reagents or enzymes used in nucleic acid manipulation wherein the first layer comprises PVP or PVPP and the second layer is adapted to separate a plurality of nucleic acid molecules with respect to size, the first layer is a first phase of a gel and the second layer is a second phase of a gel wherein the first layer is arranged above the second layer. Please note: arguments based on the proposed claim amendments which have not been entered (e.g. the new limitation "wherein said second layer is substantially free of PVP when said first layer comprises PVP and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP" of claim 40, etc.) are not addressed.

Applicants' arguments are not convincing since the teachings of Coffman and Berthelet et al. render the device of the instant claims *prima facie* obvious.

Coffman teaches a two phase column comprising a top layer of adsorptive media and a second layer of size exclusion media wherein various adsorptive media can be utilized including commercially available reagents comprising agarose and the first adsorptive layer is utilized to extract various components of the sample including proteins (i.e. second layer substantially free of proteins, etc.) wherein proteins can be separated from DNA and/or RNA (please refer to the entire specification particularly the abstract; pages 2- 10; Figures 1-2).

Berthelet et al. teach utilizing PVPP columns to extract DNA from soil samples and the advantages of utilizing PVP or PVPP in DNA extraction from soil samples (i.e. removing inhibitory humic acid contaminants; please refer to the entire reference particularly the abstract; Materials and Methods section; paragraph spanning left and right columns of page 20).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Patent Examiner, Art Unit 1639

January 22, 2009